

MAY 26 2000

K601397

**510 (k) SUMMARY  
AS REQUIRED BY SECTION 807.92(C)**

Identification: QuickScreen Pro Drug Cup – Model 9195X

Description: Immunoassay for the qualitative detection, Amphetamine, THC, Cocaine, PCP, Methamphetamine, Benzodiazepines, Barbiturates, Methadone and Opiates in urine

Name Of Manufacturer: Phamatech  
9265 Activity Road #112  
San Diego, California 92126, USA

Intended Use: QuickScreen Pro Drug Cup is a rapid, qualitative immunoassay for the detection of the target drugs/drug metabolites in urine. The cut-off concentrations of this test are as follows: methamphetamine; 1000 ng/ml, amphetamine; 1000 ng/ml, THC; 50 ng/ml, cocaine; 300 ng/ml, PCP 25 ng/ml, benzodiazepines; 200 ng/ml, barbiturates; 200 ng/ml, methadone 300 ng/ml and opiates; 2000 ng/ml. This assay is intended to assist in the prevention of drug abuse

Technology: The QuickScreen Pro Drug Cup, like many commercially available drug screening test kits, qualitatively measures the presence of target drugs or their metabolites by visual color sandwich one step immunoassay technology. Examples of such predicate devices include the Phamatech QuickScreen At Home DrugTest and the Phamatech QuickScreen Pro Multi Drug ScreeningTest. All of the above devices rely on the basic immunochemical sandwich assay principle of recognition and formation of specific antibody / target drug / antibody / complexes.

Performance: The product performance characteristics of the QuickScreen Pro Drug Cup were evaluated in a clinical sample correlation study and a blind labeled spiked study. The results of these studies demonstrate the Phamatech QuickScreen Pro Drug Cup to be substantially equivalent to the reported performance characteristics of other commercially available tests for the qualitative detection of the stated target drugs in urine. Correlation studies, using clinical specimens, produced a >98% correlation when compared to the QuickScreen Pro Multi Drug Screening Test (Model 9153 PAT04) and GC/MS methodology. Clinical studies, performed at two independent laboratories, were also performed. In them the Phamatech QuickScreen™ Pro Drug Cup exhibited excellent overall accuracy (>97%) in the hands of professional users.

Conclusion: For the reasons mentioned above, it may be concluded that the Phamatech QuickScreen Pro Drug Cup is substantially equivalent to a variety of detection tests currently in commercial distribution and is safe in the hands of the professional user.



DEPARTMENT OF HEALTH & HUMAN SERVICES

**MAY 26 2000**

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Mr. Carl A. Mongiovi  
Vice President  
Phamatech  
9265 Activity Road, #112-113  
San Diego, California 92126

Re: K001397  
Trade Name: QuickScreen™ Pro Drug Cup (Model 9195X)  
Regulatory Class: II  
Product Code: DKZ, LDJ, LCM, LAF, DIO, DJG, DJR, DIS, JXM  
Dated: April 26, 2000  
Received: May 3, 2000

Dear Mr. Mongiovi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

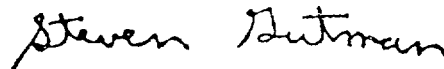
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large, stylized 'S' and 'G'.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## INDICATIONS FOR USE

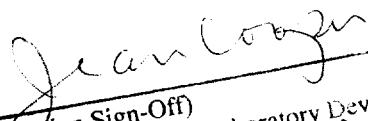
Applicant: Phamatech

510 (k) Number (if known): K 001397.

Device Name: QuickScreen Pro Drug Cup (Model 9195X)

Indications for Use:

An in vitro diagnostic test for the qualitative identification of amphetamine, cocaine, methamphetamine, opiates, PCP, benzodiazepines, barbiturates, methadone and THC in urine. Measurements obtained by this device are used in the diagnosis and treatment of drug abuse. It is intended for professional use only.

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K001397

PLEASE DO NOT WRITE BELOW THIS LINE

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Concurrence of the CDRH Office of Device Evaluation (ODE)

Division Sign-off  
Division of Clinical Laboratory Devices  
510 (k) Number:

Prescription Use: ✓ OR  
Per 21 CFR 801.109

Over the Counter: \_\_\_\_\_